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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,234	06/09/2006	Florence Guimberteau	09471.0018	1618

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EXAMINER	
EBRAHIM, NABILA G	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,234	GUIMBERTEAU ET AL.	
	Examiner	Art Unit	
	Nabila G. Ebrahim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/25/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt of Information Disclosure Statement dated 01/25/2005 is acknowledged.

Claim Rejections - 35 USC § 112

1. Claims 1-13 are rejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph.

The claim(s) are narrative in form and replete with indefinite and functional or operational language. The structure which goes to make up the device must be clearly and positively specified. The structure must be organized and correlated in such a manner as to present a complete operative device. The claim(s) must be in one sentence form only. Note the format of the claims in the patent(s) cited.

2. Claims 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is generally confusing and the subject matter is ambiguous. For example the claim recites "a film-forming polymer insoluble in gastrointestinal tract fluids". If the claim recites that the microcapsule is administered orally, and then recites that it is not soluble in the gastrointestinal tract, then where would the active agent be beneficial to the body. Please note that the GI tract extends from the mouth opening and ends at the anal opening.

For expediting the examination of the claims, the Examiner will interpret the claims as best understanding possible.

3. Claim 12 and 13 are provides for "the use of microcapsules for the modified release of at least one active principles ..", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 12 and 13 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Objection

4. Claims 3- 11 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims are demonstrating multiple dependencies.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/522252.

'252 is drawn to microcapsules, each having a core which contains an active agent and a solubilizing agent, and surrounded by a coating made of two types of polymers, plasticizers and lubricants. The active agents are the same and the microcapsules have the same size. The amount of ingredient is the same and the structure of the microcapsule is also the same.

This is a provisional obviousness-type double patenting rejection.

3. Claims 1-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 11/583940.

'940 is drawn to microcapsules, each having a core which contains an active agent and a solubilizing agent, and surrounded by a coating made of two

types of polymers, plasticizers and lubricants. The active agents are the same and the microcapsules have the same size. The amount of ingredient is the same and the structure of the microcapsule is also the same.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2 and 4-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Mehta US 5084278 (Mehta). .

Mehta teaches microcapsule with a core wherein the core comprises an active agent and a diluent (corresponds to the solubilizing agent in the instant claims). The core is surrounded by a coating which comprises a film-forming polymer (abstract). preferred coating composition is a mixture comprised of at least about 5% of a high temperature film forming polymer and about 5% of a low temperature film forming polymer based on the total weight of polymer in the microcapsule coating (col. 4, lines 24+). A preferred high temperature film forming polymer can be ethyl cellulose (col. 5, line 21), note that since the same polymer is used with the active agent in the core, it should be capable of increasing the solubility of the at least one active principle by more than 50% as required by instant claim 1. The low temperature film forming polymer can be any

of a group of plasticizers including glyceryl triacetate polyvinyl pyrrolidone (col. 5, lines 41+). The microcapsules are 0.25-1 mm in diameter (col. 2, lines 21-22). The diluent added to the core material may be hydroxypropyl or hydroxypropyl methyl cellulose, polyvinyl alcohol, and polyvinylpyrrolidone among others (col. 8, lines 10+). Mehta also discloses the use of lubricants such as magnesium stearate (col. 8, line 14). The microcapsules can be prepared to release the active agent in the intestine (col. 6, lines 33-34), the disclosure is understood as the coating polymer is not soluble in the stomach as required in the instant claims. The drugs that can be comprised in the core are antibiotics, and ibuprofen among others (col. 7, lines 48+). It is noted that since Mehta teaches the same microcapsule ingredients in the same structure and amounts, and since the mass fraction is calculated as:

Mass fraction (w_A) is the ratio of the mass of substance A to the total mass of a mixture.

It is expected that Mehta's ingredient mass fraction would have the same value recited in the claims.

Regarding the release profile recited in claim 12, absent of evidence on the contrary, the burden is shifted to applicant to show that the microcapsules taught by Mehta would not exhibit the claimed properties. It is noted that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15

USPQ2d 1655, 1658 (Fed. Cir. 1990). In the instant application, Mehta teaches the use of the same coating composition comprising the same ingredients, and in the same concentrations.

Thus Mehta anticipated instant claims 1-2, and 4-13.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of

35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta US 508427, in view of Mulye US 6946146 (Mulye).

Mehta is relied upon for the reasons set forth hereinabove

Mehta does not explicitly teach the amount of the claimed lubricant surfactant.

Mulye teaches coating for sustained release pharmaceutical composition. The coating composition of the invention may be used to coat various cores or substrates containing the active ingredient such as tablets, spheroids (or beads), microspheres. The dosage form contains cores which contain the medicament or therapeutically active agent which is administered to a mammal. The coating layer may include a lubricant. Examples of suitable lubricants include calcium stearate, colloidal silicon dioxide, magnesium stearate, aluminum stearate, or a mixture of any two or more of the forgoing, and the like. If present, the lubricant is present in amounts ranging from about 0.01% to about 10% by dry weight of the coating (col. 8, lines 38+).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the microcapsule of Mehta using a lubricant in an amount around the percentage disclosed by Mulye in the coating because Mehta teaches microcapsules having sustained/modified release profiles. The expected results would be an orally administered microcapsule having cores containing an active agent and a solubilizing compound and having

a coating which comprises two kinds of polymers, one is a film forming and not soluble in the stomach and the other is water soluble, a plasticizer and a lubricant.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nabila Ebrahim
12/29/07

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER